**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF PENNSYVLANIA**

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| JILL SIKKELEE, Individually and as Personal Representative of the ESTATE OF DAVID SIKKELEE, Deceased, | : | Case No. 4:07-cv-00886-MWB |
| Plaintiff | : | Judge Matthew Brann |
| v. | : | |
| PRECISION AIRMOTIVE CORPORATION, et al., | : | |
| Defendants | : | |

**PLAINTIFF'S SUPPLEMENTAL BRIEF REGARDING CONFLICT PREEMPTION**

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## SUPPLEMENTAL BRIEF

This brief fleshes out responses to questions that arose at the oral argument on Lycoming's conflict preemption motion. To win its defense, Lycoming must make two independent showings. First, it must show that the Federal Aviation Administration (FAA) "made an affirmative determination with respect to the challenged design aspect," "expressly approv[ing]" of it during the type certification process. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 702 (3d Cir. 2016) (quoting the FAA's brief). Second, Lycoming must show that federal law prohibits it from deviating from the challenged design, so that its position is analogous to that of generic drug manufacturers who are required by federal law not to alter the labels on their drugs. *Id*. While the court of appeals did not "demarcate the boundaries of those tort suits that will be preempted as a result of a conflict between state law and a given type certificate, nor which FAA documents incorporated by reference in a type certificate might give rise to such a conflict," *id*., it clearly stated that "[f]ederal law does not preempt state design defect claims," *id*. at 696, that "the type certification process cannot as a categorical matter displace the need for compliance . . . with state standards of care," *id*., and that Congress did not intend for "the mere issuance of a type certificate [to] exempt[] designers and manufacturers of defective airplanes from the bulk of liability for both individual and large-scale air catastrophes," *id*.

Lycoming cannot satisfy either prong of the Third Circuit's test. Indeed, Lycoming has not even attempted to show that the FAA made an "affirmative determination" about *its* decision to secure the throttle-body-to-bowl screws in the MA-4SPA carburetor using lock tab washers—because it cannot point to any express approval of that aspect of its design during the type certification process. Instead, Lycoming has argued that Kelly Aerospace, Inc.—the Parts Manufacturer Approval (PMA) holder and repair station that overhauled the carburetor in the accident aircraft—obtained the FAA's approval for the designs of its screws, lock tab washers, and gaskets, and that conflict preemption applies because Kelly was prohibited from altering the design of those component parts.

Lycoming's argument fails on its own terms, and also because it misapprehends the law. We begin with a few overarching issues that should frame the Court's analysis of the motion. Second, we address Lycoming's argument head-on, explaining why Kelly had the ability to build the carburetor in the accident aircraft differently without prior FAA approval—and also why the FAA approval stamps on Kelly's individual part drawings do not constitute the sort of "affirmative determination" that gives rise to conflict preemption in the first instance. Third, we explain why controlling precedent weighs strongly against conflict preemption here. Finally, we explain why rejection of Lycoming's conflict preemption motion would not bolster its other defenses.

## I. Lycoming's Conflict Preemption Motion Faces a Steep Uphill Climb.

To overcome the presumption against preemption, Lycoming must show that "Congress expressed its clear and manifest intent to preempt aviation products liability claims." *Sikkelee*, 822 F.3d at 692. But "the indicia of congressional intent . . . point overwhelmingly the other way." *Id*. at 698-99. As Congress itself has explained, "[t]he liability of general aviation aircraft manufacturers is governed by tort law . . . ultimately grounded in the experiences of the legal system and values of the citizens of a particular State." H.R. Rep. No. 103-525(II), at 3-4 (1994). Congress has therefore always "tread[ed] very carefully when considering proposals . . . that would preempt State liability law." *Id*. at 4. When Congress enacted an 18-year statute of repose in the General Aviation Revitalization Act (GARA), it "was willing to take the unusual step to preempting State law in this one extremely limited instance." *Id*. at 6. That limited preemption was justified because "***any design*** or manufacturing ***defect*** not prevented or identified by the Federal regulatory process by [year 18] should, in most instances, have manifested itself," making civil liability unnecessary. *Id*. (emphasis added). However, "in cases where the statute of repose has not expired," Congress declared that "State law will continue to govern fully, unfettered by Federal interference." *Id*. at 7. Consistent with these statements, no court has *ever* allowed a manufacturer like Lycoming to escape liability for a defective design on conflict preemption grounds—even though such tort claims have

been brought for decades (indeed, their prevalence was the impetus for GARA).[1]

Against that backdrop, Lycoming asserts impossibility preemption—a particularly "demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). As with all affirmative defenses, Lycoming bears the burden of proof. That burden is heightened at summary judgment because all reasonable inferences must be drawn in our favor, and Lycoming must prove that no reasonable jury could reject the factual premises of its defense. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 295 (3d Cir. 2017). In this summary judgment posture, the Court must assume that Lycoming's design is defective, and caused the crash that killed David Sikkelee (a proposition supported by abundant record evidence). It must further assume that alternative designs cure that defect while complying with federal airworthiness standards (a proposition that Lycoming has not disputed). To win, Lycoming must show that, notwithstanding those assumptions, if it or Kelly had attempted to comply with state law by altering the engine and/or carburetor in this case, every reasonable jury would find a high probability that the FAA would have prohibited the change. *See id.* Lycoming cannot meet that standard.

[1] Courts that have considered the defense have rejected it. *See, e.g.*, *Davidson v. Fairchild Controls Corp.*, No. CV H-15-0827, 2016 WL 5539982, at *8 (S.D. Tex. Sept. 29, 2016) (holding that "conflict preemption . . . does not apply" because "the minimum standards of the federal aviation regulations do not prohibit the design and manufacture of safer aircraft and component parts"); *see also Monroe v. Cessna Aircraft Co.*, 417 F. Supp. 2d 824, 836 (E.D. Tex. 2006); *Holliday v. Bell Helicopters Textron, Inc.*, 747 F. Supp. 1396, 1401 (D. Haw. 1990).

## II. Limitations on Kelly Do Not Support Conflict Preemption.

1. Lycoming argues that because the FAA approved the design of Kelly's PMA screws, lock tab washers, and gaskets, and because Kelly could not change those designs without FAA approval, conflict preemption applies. At argument, Lycoming also emphasized Kelly's role as a repair station—which is distinct from its status as a PMA holder—and argued that as a repair station, Kelly was required by the FAA to install the MA-4SPA carburetor as designed. Tr. 14, 52, 59, 62. We have already addressed Kelly's ability as a PMA holder to change its own designs. Doc. 545, at 14-15. Here, we explain that as a repair station, Kelly was able to make "alterations," to individual aircraft, deviating from the type design on a one-off basis without prior FAA approval. That flexibility gave Kelly another way to comply with both state and federal law, and thus independently defeats Lycoming's defense.

An alteration is any change to a single regulated aircraft, engine, or propeller. The regulations classify alterations as "minor" or "major."[2] Minor alterations "do not require [FAA] approval." FAA, Major Repair & Alteration Data Approval, Order 8300.16, at 5 (2014); *see also id.* at 2. Instead, the repair station "performs"

[2] A "major alteration" is one "not listed in the aircraft, aircraft engine, or propeller specifications—(1) That might appreciably affect weight, balance, structural strength, performance, powerplant operation, flight characteristics, or other qualifies affecting airworthiness; or (2) That is not done according to accepted practices or cannot be done by elementary operations." 14 C.F.R. § 1.1. A "minor alteration" is any other alteration. *Id.*; *see also* FAA, Advisory Circular 120-77, at Appx 1 (2002).

the "alteration and documents [it] in maintenance records," without any FAA input. *Id*. at 4 (Figure 3-1). Changing the attachment mechanism in the MA-4SPA carburetor from lock tab washers to safety wire would qualify as "minor" because the use of safety wire is common, can be done by any trained mechanic, and would not adversely affect the weight, balance, structural strength, performance, powerplant operation, or other qualities affecting airworthiness of the engine.[3] Consequently, federal law permitted Kelly to make that alteration to the engine without prior FAA approval, and Lycoming's motion fails for that reason alone.

Lycoming has not even argued that the required changes to its design would be "major"—but even major alterations can be implemented without prior FAA approval if the "technical data" has previously been approved. *Id*. "Technical data" means "the drawings, specifications, and other material that provide the description and substantiation of an aircraft repair or alteration." *Id*. at 12. "Previously approved" data includes airworthiness directives; "DER-approved data"; "service bulletins . . . or similar documents;" and "[m]aintenance manuals issued by design and production approval holders." *Id*. at 14. When such data is available, "further review or approval of that data would not be necessary." *Id*. at 13. Similarly,

[3] Lycoming has never disputed that if it changed its type design from lock tab washers to safety wire, the change would be "minor" under 14 C.F.R. § 21.93(a) because it would have "no appreciable effect on the weight, balance, structural strength, reliability, operational characteristics, or other characteristics affecting the airworthiness of the product." This reasoning supports a minor alteration finding too.

"[m]inor deviations from previously approved data do not require re-approval." *Id*. at 15. An applicant can also employ a DER "prior to involving the FAA," and if "the applicant has determined that the DER has provided all the approved data necessary for the repair or alteration, then no [FAA] field approval is required." *Id*. at 40.

If Lycoming had changed its type design—by, for example, using safety wire instead of lock tab washers—Kelly easily could have followed suit because features "listed in the" manufacturer's "specifications" for the engine are never "major alterations," and never require FAA approval. 14 C.F.R. § 1.1. Second, if Lycoming had changed its design and issued guidance urging the use of safety wire, that guidance would have constituted "previously approved" data that Kelly could have relied upon to make even a major alteration. Moreover, the safety wire method was previously required on MA-4SPA carburetors by an airworthiness directive. Doc. 546, ¶ 27 & n.2. Kelly could have relied on that "previously approved" data to support an alteration as well. Or it could have obviated the need for FAA approval by employing a DER holding the proper delegations (either as an employee or as a consultant) to approve the data. Kelly did not take those steps, however, because Lycoming demanded a different design for carburetors in the O-320-D2C engine.

2. Independently, Lycoming is wrong to treat the FAA's approval of Kelly's drawings of screws, lock tab washers, and gaskets as an "affirmative determination" by the agency that lock tab washers constitute the only appropriate way to secure the

throttle-body-to-bowl screws in an MA-4SPA carburetor. As Lycoming's counsel acknowledged at argument, MA-4SPA carburetors can have different "configurations that are on different type certificated engines." Tr. 134. Thus, it cannot be said that the FAA has affirmatively determined that there is only one appropriate design for the carburetor. The fact that Kelly used this particular design for this engine is a function of Lycoming's design choices, not an FAA edict.

Moreover, the FAA's approval of Kelly's replacement screws, washers, and gaskets does not constitute an "express approval" or "affirmative determination" that the carburetor design is appropriate, let alone mandatory, under federal law. Kelly never designed an entire carburetor; it only designed certain replacement parts. Lycoming presented Kelly's drawings of individual parts featuring FAA approval signatures (Docs. 533-1-4), but those stand for nothing more than a finding that the parts meet applicable airworthiness requirements because tests showed that they have the same form, fit, and function as OEM (Lycoming and Marvel Schebler) parts. Doc. 533 ¶ 11; Doc. 546 ¶¶ 36-38. That approval allows those parts to be installed as replacements for OEM parts on a Lycoming engine. Doc. 533 ¶¶ 16-19. But it does not reach back to approve all aspects of the fuel system (*i.e.*, carburetor) design, and Lycoming has never presented a similar signed drawing of that design feature. Thus, while Kelly's individual approvals may *assume* that the carburetor design is airworthy, they do not establish that fact. Under the Third Circuit's test,

conflict preemption requires more than a mere assumption by the agency; it requires an "express[] approv[al]" or "affirmative determination." *Sikkelee*, 822 F.3d at 702.

## III. Controlling Precedent Weighs Heavily Against Conflict Preemption.

1. At argument, the Court asked whether cases relating to automobiles and boats might be relevant. Tr. 191. Those cases deal principally with "obstacle preemption," which Lycoming has not asserted. Nevertheless, they weigh in our favor because they hold that when Congress sets minimum standards (or directs an agency to set such standards) for products, it does not thereby preempt tort claims requiring a higher standard. *See, e.g.*, *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 335 (2011) (holding that conflict preemption is inappropriate when a federal agency "seeks only to set forth a *minimum* standard potentially supplemented through state tort law"); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67 (2002) (holding that the Coast Guard's refusal to require propeller guards did not preempt a lawsuit because the refusal did "not convey an 'authoritative' message of a federal policy against propeller guards"); *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 870 (2000) (explaining that the statutory saving clause "preserves those actions that seek to establish greater safety than the minimum safety achieved by a federal regulation"). Instead, it is only when Congress or the agency intend to set both a ceiling and a floor that preemption may occur. *See Geier*, 529 U.S. at 874-75.

The Federal Aviation Act is indistinguishable from the statutes that did not give

rise to preemption. It, too, contains limited express preemption clauses (the Airline Deregulation Act and GARA, neither of which apply here), and a saving clause that preserves state law remedies, 49 U.S.C. § 40120(c); *Am. Airlines, Inc. v. Wolens*, 513 U.S. 219, 222 (1995). Moreover, the statute only requires the FAA to promulgate "minimum standards" for type certification, 49 U.S.C. § 44701(a), and the Third Circuit held that these standards are "baseline requirement[s]" that states are free to exceed. *Sikkelee*, 822 F.3d at 695. Furthermore, there is no evidence that Congress or the FAA intended for certification decisions to prevent the development or implementation of safer designs. Instead, Congress sought to ensure "the highest degree of safety in air transportation," 49 U.S.C. § 40101(a)(3).

2. At argument, the parties also disagreed about whether this case more closely resembles brand-name drug manufacturer cases like *Wyeth*, which rejected conflict preemption—or generic drug manufacturer cases like *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), which found preemption. We argued that this case is more like *Wyeth* because general aviation manufacturers have substantial autonomy to change their designs, similar the authority granted to brand-name manufacturers by the FDA's "changes being effected" regulation. Tr. 152-53. Lycoming compared the case to *Bartlett* because "*Bartlett* is an actual design defect case not a warning case," and this case likewise involves design defects. Tr. 147.

Lycoming's premise and conclusion are both wrong. First, the Supreme Court

rejected the premise that *Bartlett* was "not a warning case." Although the plaintiff attempted to characterize her claim that way in order to distinguish *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), the Court explained that "redesign [of sulindac, the generic drug] was not possible" either legally or as a matter of chemistry, and so "the only way for Mutual . . . to escape liability—was to strengthen" the warning on the drug's label. *Bartlett*, 133 S. Ct. at 2475. Because "New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings," *id*., the Court held that "New Hampshire's warning-based design-defect cause of action is pre-empted" under *PLIVA, id*. at 2477.

Second, even if *Bartlett* had been a design defect case, it does not follow that *Bartlett* controls here. *Wyeth* and *Bartlett* reached different results—but not because the former dealt with labels and the latter product design. The critical fact was that in *Wyeth* federal law allowed the manufacturer "to make certain changes to its label before receiving the agency's approval," 555 U.S. at 568, but in *Bartlett* "federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law" because "federal law prevents generic drug manufacturers from changing their labels." 133 S. Ct. at 2476. It was the nature of the applicable federal regulations—and not the nature of the plaintiff's claim—that mattered.

On the relevant axis, then, this case resembles *Wyeth* because federal law permits Lycoming and Kelly to make certain changes that state law requires them to make:

Lycoming can make minor changes to the type design without consulting the FAA; and repair stations like Kelly can make all minor and some major alterations to individual carburetors without FAA approval. Thus, the regulations here resemble the CBE regulation at issue in *Wyeth*, not the generic manufacturer regulations at issue in *Bartlett*—and the preemption analysis should track that of *Wyeth*.

Separately, this case is distinguishable from *Bartlett* because it was impossible for the generic drug manufacturer to alter the composition of sulindac (which is a single molecule), but the same is not true of the O-320 engine. We have shown that Lycoming already has the ability to produce multiple variants of the O-320 engine that do not contain the design defect that killed David Sikkelee: two of the variants use different carburetors; and dozens more use fuel injection instead of carburetion. Tr. 133-34. That dooms Lycoming's impossibility argument because Lycoming cannot explain why federal law requires it to produce the O-320-D2C variant, as opposed to other variants of the O-320 that comply with both state and federal law.

We have also explained that in deciding whether to apply *Wyeth* or *Bartlett*, the question should not be whether the case is indistinguishable from either of those—but instead which one it more closely resembles. Tr. 124-25. As *PLIVA* explains, "whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine." 564 U.S. at 623. The Court found no difficulty in the generic drug cases because:

> Before the Manufacturers could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

*Id*. at 623-24. As the Court explained in *PLIVA*, generic manufacturers were effectively powerless to change their label: they could only do so through a complex, multi-step "Mouse Trap game," *id*. at 619, and there was "no evidence of any generic drug manufacturer ever" even attempting to do so, *id*. at 617.

This case is different. Here, it is undisputed that had Lycoming sought to make a change, it would not have had to obtain approval from any FAA employee. Instead, the most that Lycoming would have needed would have been the signature of a DER—a Lycoming employee. Although DERs act as surrogates for the FAA, their approval does not constitute a "special effort" by a "federal agency," nor does it require the "federal agency" to exercise any "judgment." *PLIVA*, 564 U.S. at 623-24. Instead, the judgment of the private DER substitutes for the judgment of the agency itself. *See, e.g.*, 14 C.F.R. § 183.29(e) (explaining that a DER "may approve engineering information relating to engine design . . . whenever the representative determines that information complies with the applicable regulations"). Indeed, the entire point of the DER program is to conserve federal resources by taking the agency out of "routine certification tasks." FAA, About the Designee Program, http://tinyurl.com/y8owhcke (last visited June 16, 2017). Moreover, in contrast with

the unprecedented "Mouse Trap game" described in *PLIVA*, DER approvals of type design changes are routine: a 2004 GAO report stated that designees perform "more than 90 percent of FAA's certification activities." GAO, *Aviation Safety: FAA Needs to Strengthen the Management of its Designee Programs*, GAO-05-40, at 3 (2004). Indeed, DERs approved the change to lock-tab washers for Marvel Schebler and Lycoming. Doc. 234-12; Doc. 546-1.

Lycoming has argued that DER approval is nevertheless FAA approval, and that the need for a DER signature therefore prevents Lycoming from acting unilaterally to comply with state law. But Lycoming cites no authority for the proposition that when a manufacturer can obtain regulatory approval by consulting *its own employees*, and even when (as here) that approval is certain to be granted, it can assert "impossibility." Moreover, Lycoming's description of DER approval is dubious. While DER approval does have the same practical effect as approval by the FAA itself (because the DER exercises authority delegated by the FAA), the FAA's handbook for DERs regularly distinguishes between the two, and at one point goes so far as to state that "[a] DER's signature does not constitute FAA approval." FAA, Designated Engineering Representative (DER) Handbook, Order 8110.37E, at 16 (2011); *see also id.* at 15 (stating that although a DER "represents the FAA," the DER "is not an employee of the FAA . . . and is not federally protected for work done or the decisions made as a DER. As a private individual, a DER is subject to

general tort law"); *id*. at 12 (distinguishing items that can be approved by a DER, and items that "must be approved or issued by FAA employees").[4]

Lycoming has also cited the FAA's letter brief to the Third Circuit, which argued that even for minor type design changes, "the decision to approve the type design ultimately rests with the FAA." Doc. 534-1, at 15. But that fact does not distinguish this case from *Wyeth*: there, the manufacturer was allowed to implement certain labeling changes while an application for the change was pending with the FDA, but the FDA "retain[ed] authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application." 555 U.S. at 571. The Court held that "absent clear evidence that the FDA would not have approved a change," impossibility preemption was not available. *Id*. The same is true of minor changes to a type design. The regulations provide that "[m]inor changes in a type design may be approved under a method acceptable to the FAA before submitting to the FAA any substantiating or descriptive data." 14 C.F.R. § 21.95. Thus, approval plainly can occur before the FAA even has the data. FAA guidance further explains that when a regulation uses the phrase "acceptable to the FAA," the items (including "methods") so described:

[4] At argument, Lycoming disparaged this contention as an attack on the sufficiency of the DER system. Tr. 155. But we are not saying that the DER system is inadequate. All we are saying is that DERs are employees of the manufacturers, and ought to be regarded as such for purposes of deciding whether federal law permits the manufacturer to act independently.

> do not necessarily require FAA review and acceptance prior to a person using the item. A person using an item that must be acceptable to the FAA should be able to demonstrate that the item meets all applicable regulatory requirements. If, however, upon subsequent review of the item, the FAA believes the item is not acceptable, the agency has the burden of demonstrating its unacceptability in any related enforcement matter.

Order 8300.16, *supra*, at 12. Other FAA guidance elaborates that one acceptable method for minor type design changes is implementation by a DER "without prior authorization by the [Aircraft Certification Office]." Order 8110.37E, *supra*, at 24. Lycoming has never stated what methods it uses to implement minor design changes—and it is possible that a DER signature may not even be required in Lycoming's case—but at the very least, Lycoming has never disputed that it can implement changes that way, without involving FAA employees.

Separate from all that—and even if this Court believes that the need for a DER's signature might give rise to impossibility preemption—minor alterations to individual engines do not even require DER participation. *See id*. at 27 ("[M]inor alterations do not require FAA engineering approval. As such, DERs cannot approve minor . . . alterations."). As explained above, those alterations can be implemented by repair stations without *any* input from the FAA or its designees.

If the Court correctly concludes that this case is more like *Wyeth*, then Lycoming's motion must fail in light of *Fosamax*, which held that in order to win summary judgment a manufacturer must provide clear evidence that the government would reject a proposed change. 852 F.3d at 295. Lycoming has not provided clear

evidence that the FAA would have rejected a design change or alteration. Indeed, Lycoming conceded that "[t]he FAA probably would approve" a safer design—and rested its defense on the flawed argument that this fact does not matter. Tr. 135.

Even if this Court concludes that the case more closely resembles *Bartlett*, it should still find against preemption. As the United States explained, a "pure design defect claim" is not preempted if it is based on the contention that new scientific information showed that a drug was misbranded in violation of federal law. U.S. Amicus Br. 23, *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In such cases, state law duties "parallel" federal ones, and therefore do not create any conflict. *Id*. By analogy, when an aircraft engine design does not conform to federal standards, a design defect claim is not preempted either. Here, if we prove that Lycoming's design is defective because it causes an improper mix of fuel to flow into the engine, thus causing the engine to lose power, then we necessarily will also prove that the fuel system was not "designed and constructed to supply an appropriate mixture of fuel to the cylinders throughout the complete operating range of the engine under all flight and atmospheric conditions," 14 C.F.R. § 33.35(a), and our claim will parallel the federal standard. Thus, under the government's position in *Bartlett*, preemption would be inappropriate *even if* the Court deems *Bartlett* controlling (which it should not). *Cf. Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding that state law duties that parallel federal ones are not preempted).

Finally, while both parties have cited the drug manufacturer cases, it is important to note that the case for preemption here is far weaker than it is even for brand name drug manufacturers for two reasons. First, the exact text of every drug label is thoroughly scrutinized and approved by the FDA during the NDA process—which is not true for every detail of an engine's design during type certification. Second, the FDA routinely rejects drug label changes if it perceives that the change could discourage appropriate use of a beneficial drug. *Fosamax*, 852 F.3d at 274. The FAA's attitude toward design changes and alterations is *far* more permissive, and involves no balancing-type judgment. In essence, a manufacturer can obtain approval to implement almost any change it wants, as long as it can represent to the FAA that the changed product complies with applicable airworthiness limitations. *See, e.g.*, 14 C.F.R. § 21.97(a). It need not show that the change is necessary or even desirable; only that it would not violate the federal minimum standards. When, as here, a change would improve safety, the FAA will not reject it. Moreover, there is no clear counterpart in the FDA regulations to a repair station's ability to alter individual aircraft components, and so that process also is far more permissive than drug label changes. This matters because even if the FAA's prior approval was required before a design change or alteration (and Lycoming has not shown that it was), that approval was sure to be granted because the proposed modifications to Lycoming's design concededly meet airworthiness requirements. Tr. 124, 145, 170,

190. In that scenario, it would make no sense to hold that a change was "impossible," and thereby preempt state law that has effectively protected the public for decades.

## IV. The Failure of Lycoming's Conflict Preemption Defense Does Not Bolster its Other Arguments.

A final point merits brief discussion. The Court opened oral argument on this motion by asking whether, if it finds against conflict preemption because it finds that Kelly had sufficient autonomy to modify the engine, it must find in Lycoming's favor on state law grounds because Lycoming did not control Kelly's overhaul of the carburetor and therefore is not the "manufacturer." Tr. 111. The answer is "no." First, Pennsylvania courts have already stated that type certificate holders like Lycoming can be held "liable for design defects in replacement parts." *Pridgen v. Parker Hannifin, Corp.*, 916 A.2d 619, 623 (Pa. 2007). Second, the mechanism by which Lycoming controlled Kelly is not the operation of federal law, but instead its authority as the type certificate holder. To design PMA parts for Lycoming's engines, Kelly sought to show that its parts had the same form, fit, and function as Lycoming's. Doc. 533 ¶ 11; Doc. 546 ¶¶ 6, 39. When conducting the overhaul, it followed Lycoming's instructions and service bulletin, Doc. 546 ¶ 39—which Lycoming described as "mandatory," Tr. 65; Doc. 234-17, at 75. Even if Kelly was legally permitted to alter the carburetor, Lycoming's conduct—*i.e.*, its decision to adopt this design, its service bulletins and guidance pushing this design as mandatory, and its failure to disclose defects—prevented Kelly from doing so.

Finally, Lycoming should be held liable as the manufacturer of the engine. Under Section 402A of the Restatement (Second) of Torts, Lycoming is liable because the engine reached David Sikkelee in substantially the same defective condition as when it left Lycoming's possession. Lycoming has pointed out that Judge Jones found no evidence of a defect in 1969. Tr. 178. But that holding was clearly erroneous because the engine in 1969 incorporated the defective carburetor design. Tr. 181-82. Moreover, the Third Circuit's subsequent decision holding that state law standards of care apply casts substantial doubt on the prior decision because it is not clear that the court in 2012 considered state standards of care as opposed to federal ones when deciding that the engine was not defective. This Court should hold that Lycoming can be held liable as the manufacturer of the engine and its fuel system.

**V. Conclusion.**

Lycoming seeks to make history by convincing this Court to become the first to allow a general aviation manufacturer to escape liability on conflict preemption grounds. But as the Third Circuit's decision makes clear, impossibility preemption is demanding and narrow—and the facts could not be worse for Lycoming, which cites neither an express FAA approval of its decision to use lock tab washers and certain gasket materials, nor evidence that the FAA would have rejected changes or alterations to that design. This Court should decline Lycoming's invitation to break new ground, and send all of our claims to trial.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send a notification of such filing to all CM/ECF participants.

/s/Tejinder Singh

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